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Individualized Dosing With Low-Sodium Oxybate in Narcolepsy: Patient Voices From LYRICAL

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Objective

- To describe low-sodium oxybate (LXB) dosing patterns (including equal or unequal dose division, timing, and titration), adjustments to dosing regimens since enrollment, and perceptions of individualized dosing among LYRICAL participants with narcolepsy

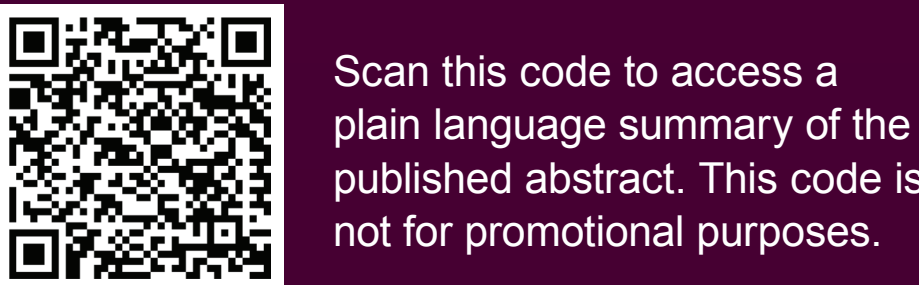
Conclusions

- Real-world data from LYRICAL highlight that people with narcolepsy value the ability to individualize their LXB dosing through shared decision-making with their healthcare providers
- Limitations include the lack of a comparator group, potential selection and recall bias (participants had been taking LXB for ≥12 weeks at enrollment), and small sample sizes for some analyses
- LXB dosing adjustments were associated with improved ratings of treatment convenience and effectiveness

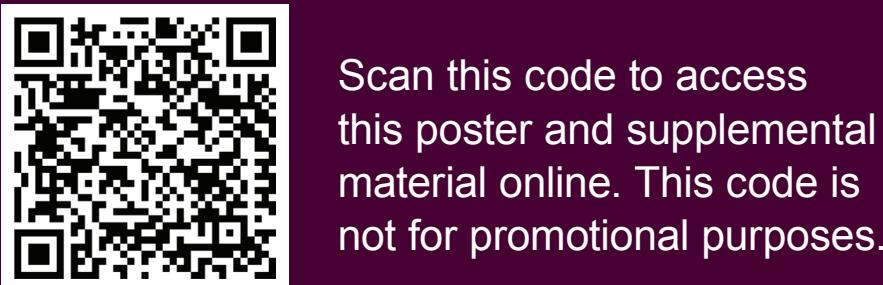
References: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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Disclosures: C Drachenberg, M Whalen, JK Alexander, S Beaty, and SC Markt are full-time employees of Jazz Pharmaceuticals who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. M Farrell, J D’Souza, E Kim, M Lawrence, and CA Graham are full-time employees of IQVIA, which received funding from Jazz Pharmaceuticals to conduct the study. LB Herpel is an Affiliate Assistant Professor at the Medical University of South Carolina; participates in clinical research for Avadel, Axsome Therapeutics, Eisai, Eli Lilly, Harmony Biosciences, Idorsia, Jazz Pharmaceuticals, LivaNova/OSPREY, Merck, Noctrix, Roche, Samsung, Sanofi, Suven, Takeda, and Vanda; serves as an advisor to Avadel, Axsome, Eli Lilly, Harmony Biosciences, and Jazz Pharmaceuticals; and serves on the speaker bureau for Avadel and Harmony Biosciences.



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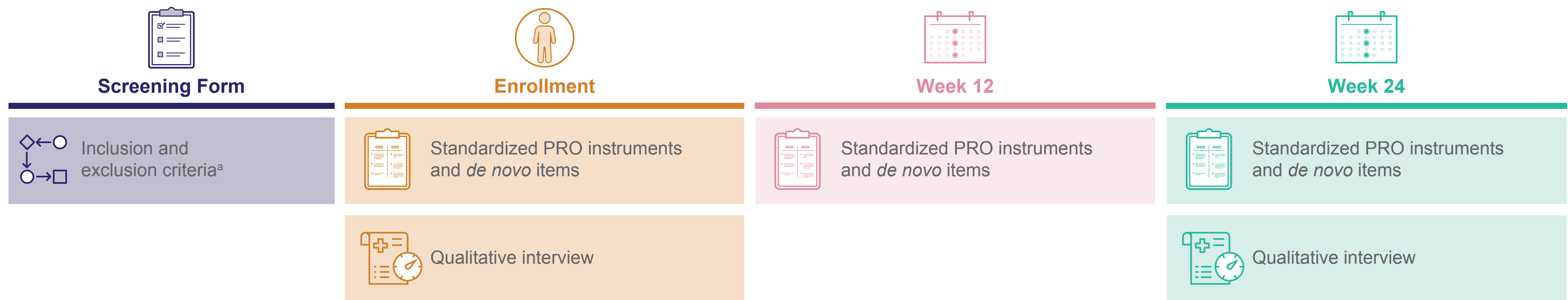
Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the US Food and Drug Administration for the treatment of excessive daytime sleepiness or cataplexy in patients 7 years of age or older with narcolepsy and for the treatment of idiopathic hypersomnia in adults¹
 - For patients with narcolepsy, LXB is an oral solution taken twice nightly in equally or unequally divided doses, administered at bedtime and 2.5 to 4 hours later; the dosage can be gradually titrated and individually optimized based on efficacy and tolerability up to the recommended dose range of 6 to 9 g/night
- Since the approval of LXB, limited real-world evidence has been published on how LXB individualized dosing may relate to treatment satisfaction from the patient perspective
- The LYRICAL (Longitudinal mixed methods study of Real-world patterns of use, effectiveness, and treatment satisfaction in adults with Idiopathic hypersomnia and narColepsy tAking Low-sodium oxybate) study was conducted to better understand the real-world experience of adults with narcolepsy or idiopathic hypersomnia taking LXB treatment
 - This poster describes LXB individualized dosing for participants with narcolepsy; LXB individualized dosing results for the idiopathic hypersomnia cohort are presented in **Poster 361**
 - Posters 359 and 360** describe participant-reported effectiveness and treatment satisfaction for LYRICAL participants with narcolepsy and idiopathic hypersomnia, respectively; **Posters 534 and 535** explore associations between daytime and nighttime symptoms and quality-of-life outcomes for LYRICAL participants with narcolepsy and idiopathic hypersomnia, respectively
 - Poster 528** explores LXB individualized dosing among participants with narcolepsy and idiopathic hypersomnia in the phase 4, prospective, single-arm, open-label DUET study

Methods

- This longitudinal, mixed-methods study gathered quantitative (survey) and qualitative (interview) data from participants currently taking LXB at enrollment and over the 24-week study period

Figure 1. LYRICAL Study Design

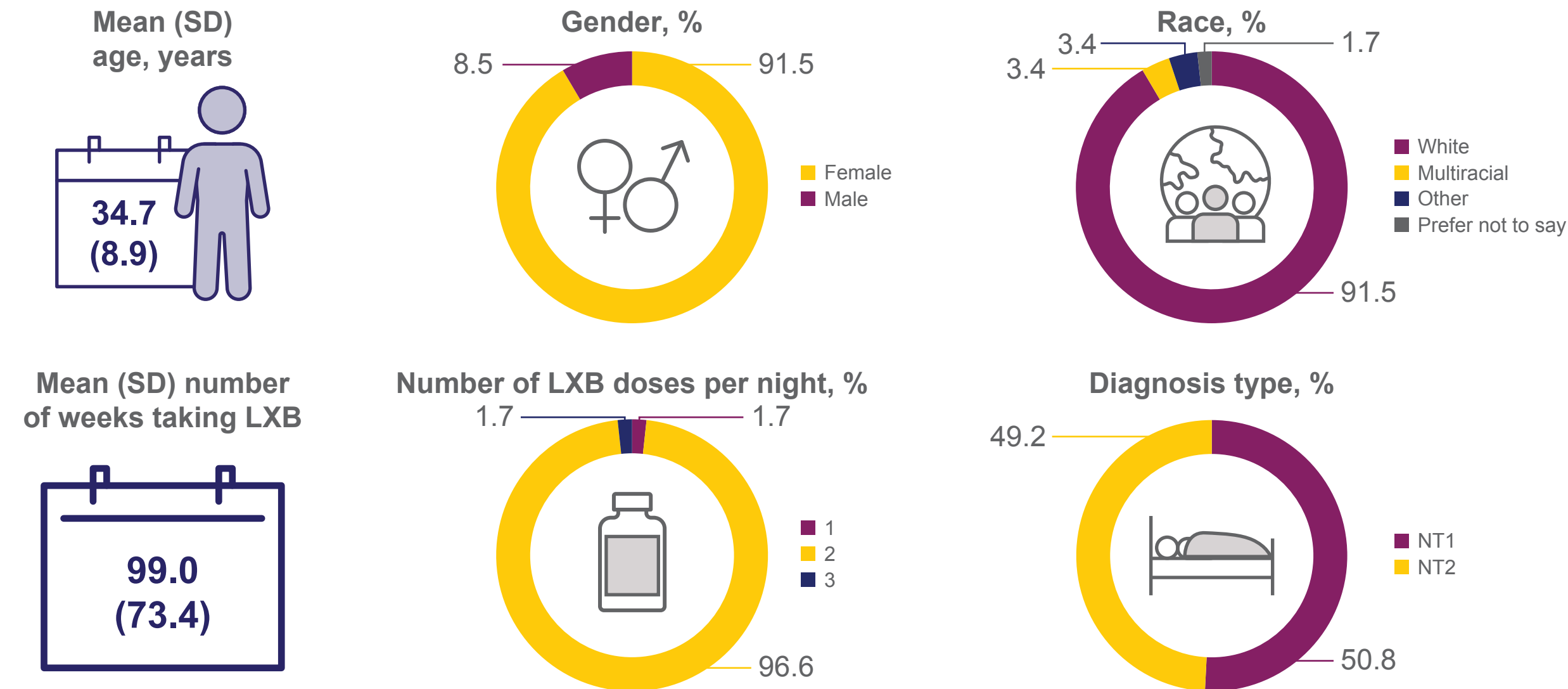


*Participants were eligible if they were ≥18 years of age at the time the screening form was completed, a US resident, diagnosed with narcolepsy or idiopathic hypersomnia, prescribed and currently taking LXB for narcolepsy or idiopathic hypersomnia, and had been taking LXB for ≥12 weeks prior to completing the screening form. All participants provided written or electronic informed consent. LXB, low-sodium oxybate; PRO, patient-reported outcome.

- Online surveys were conducted between March 2024 and August 2025 via an IQVIA-hosted platform and comprised standardized patient-reported outcome instruments (eg, Treatment Satisfaction Questionnaire for Medication [TSQM-9]) and de novo questions assessing LXB dosing patterns; surveys were administered at enrollment, week 12, and week 24
- Virtual 45-minute interviews were conducted using semi-structured discussion guides with a subset of participants at enrollment (n=15) and week 24 (n=7)
 - Interviews were audio-recorded, transcribed, and coded and analyzed using MAXQDA (VERBI Software, 2021) and Microsoft Excel
- Descriptive analyses were conducted

Results

Figure 2. Characteristics of Participants With Narcolepsy

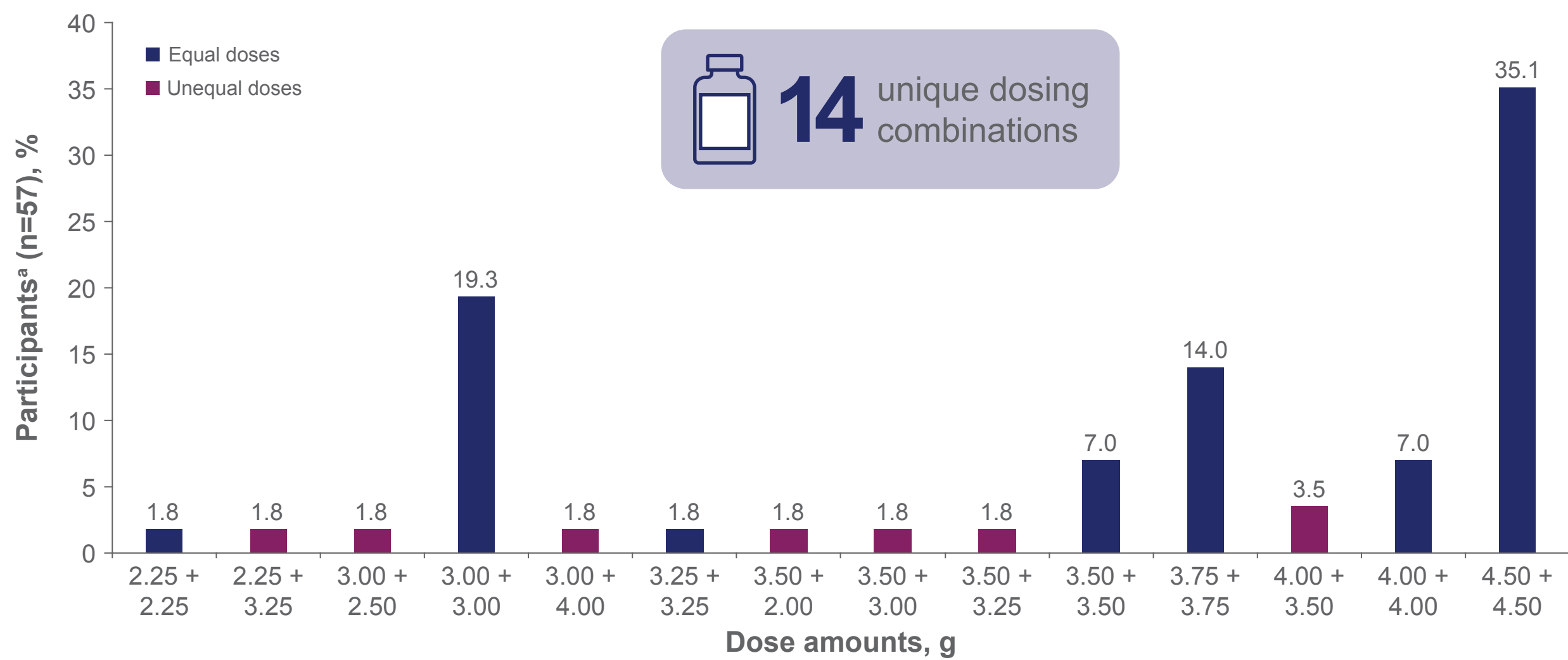


LXB, low sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.

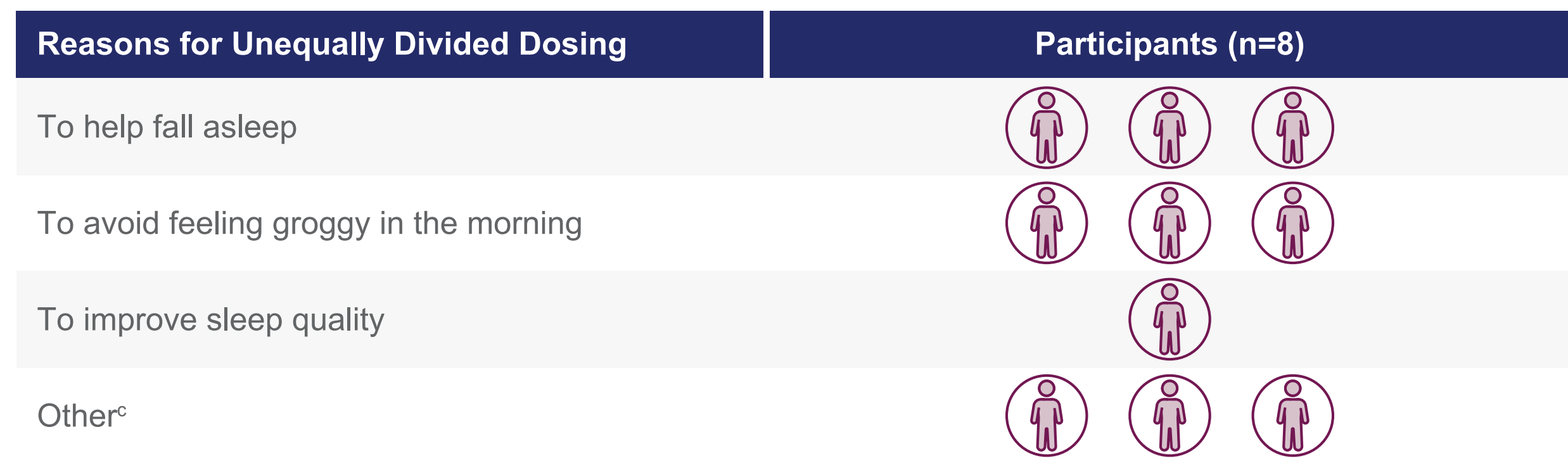
- Among 59 participants with narcolepsy, the mean age (standard deviation [SD]) was 34.7 (8.9) years
- Most participants were female (91.5%) and White (91.5%)
- Mean (SD) duration of LXB treatment was 99.0 (73.4) weeks and nearly all participants (96.6%) were taking LXB twice nightly
- The mean (SD) total nightly dosage was 7.5 (1.4) g
- Additional participant characteristics are reported in the Supplement, accessed via the QR code

Figure 3. LXB Dosing Patterns for Participants Taking LXB Twice Nightly at Enrollment

A) Participants Were Frequently Prescribed LXB Twice Nightly in Equally Divided Doses*



B) Participants Described Reasons for Being Prescribed Unequal LXB Doses*

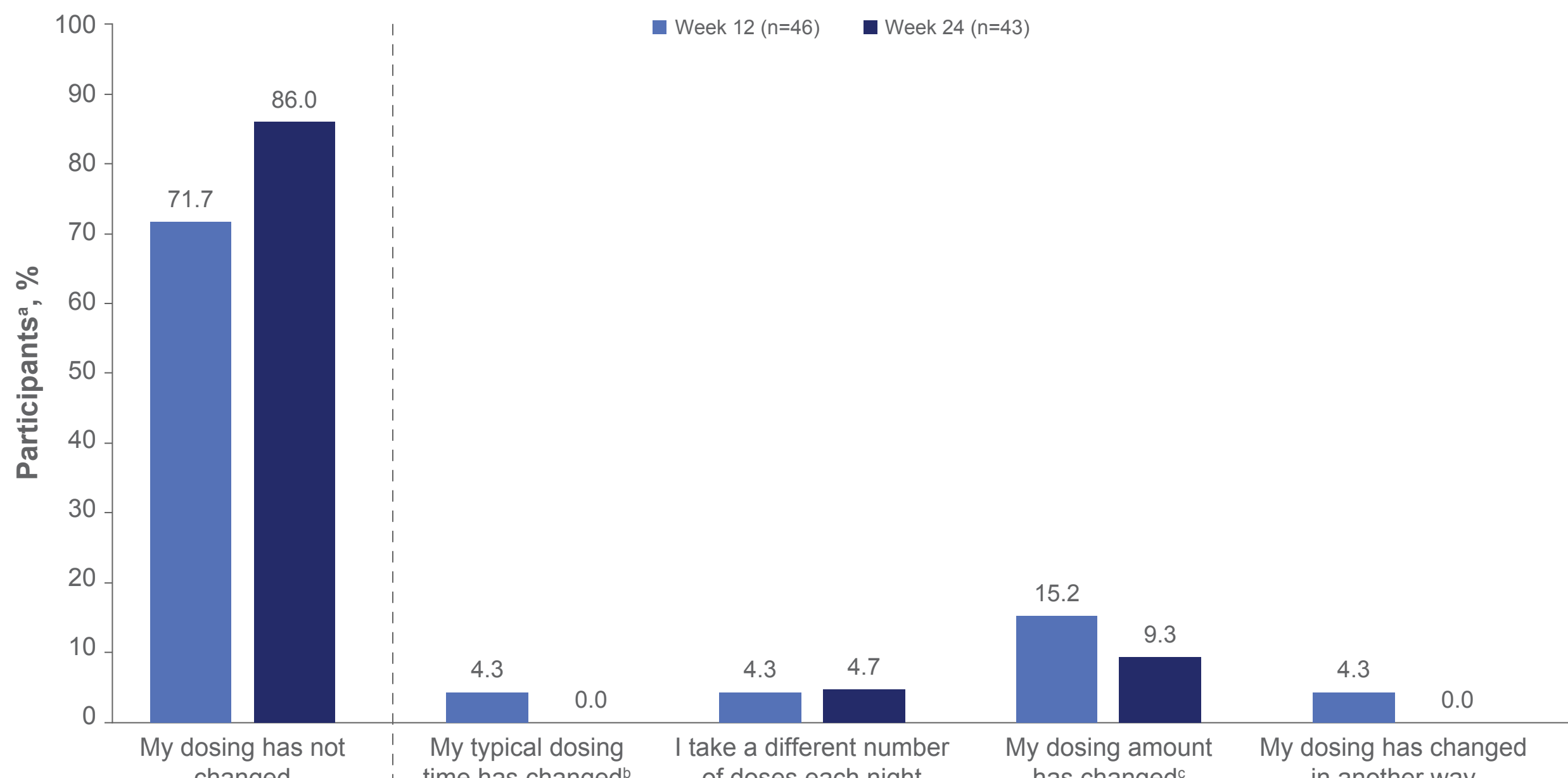


*Two participants who reported taking LXB once nightly (n=1) and thrice nightly (n=1) are not shown. ^aEach icon represents 1 participant. Participants could select multiple response options. ^bExamples of “other” reasons included “to reduce anxiety” and “to avoid oversleeping.”

LXB, low-sodium oxybate.

- Among 57 (96.6%) participants taking LXB twice nightly, 14 unique dosing combinations were utilized
 - Eight (14.0%) participants took unequal doses at enrollment, typically with a lower second dose, to support specific individual needs

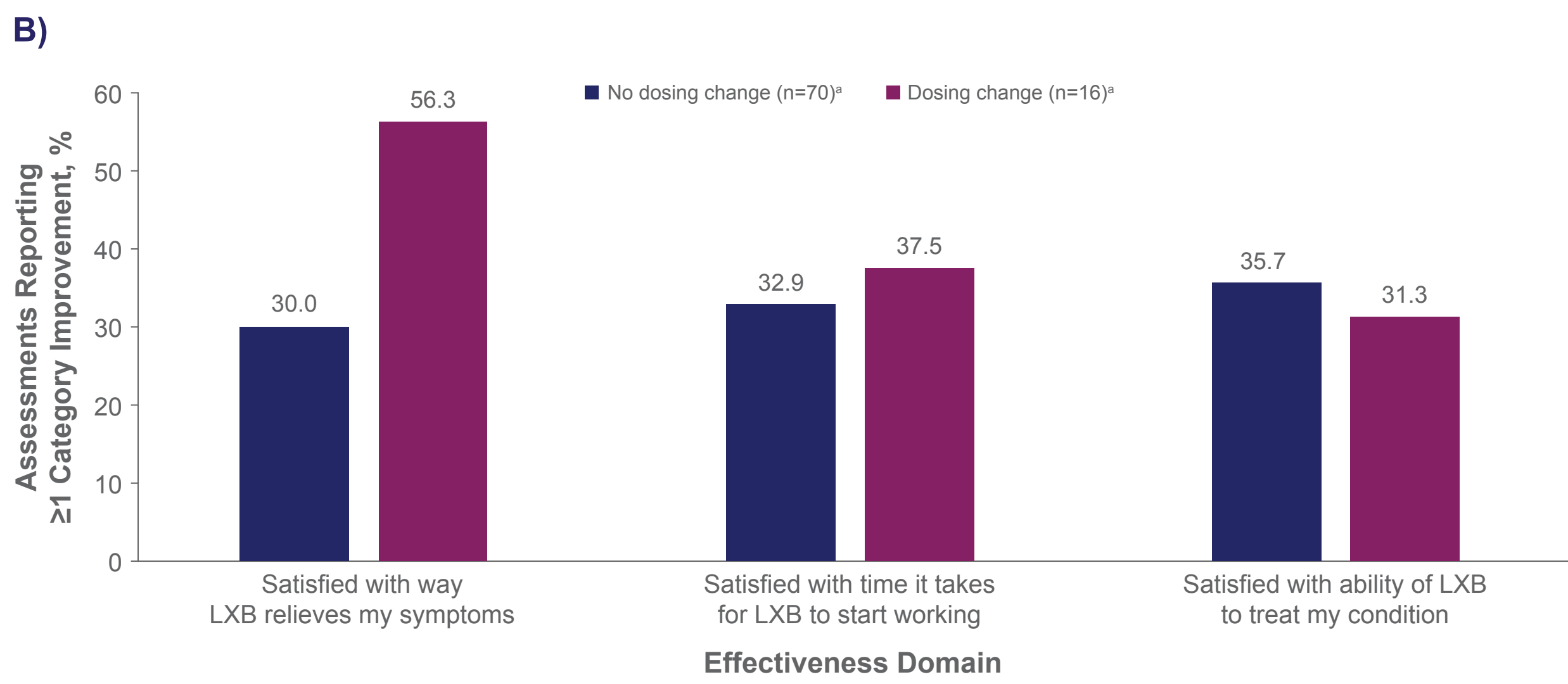
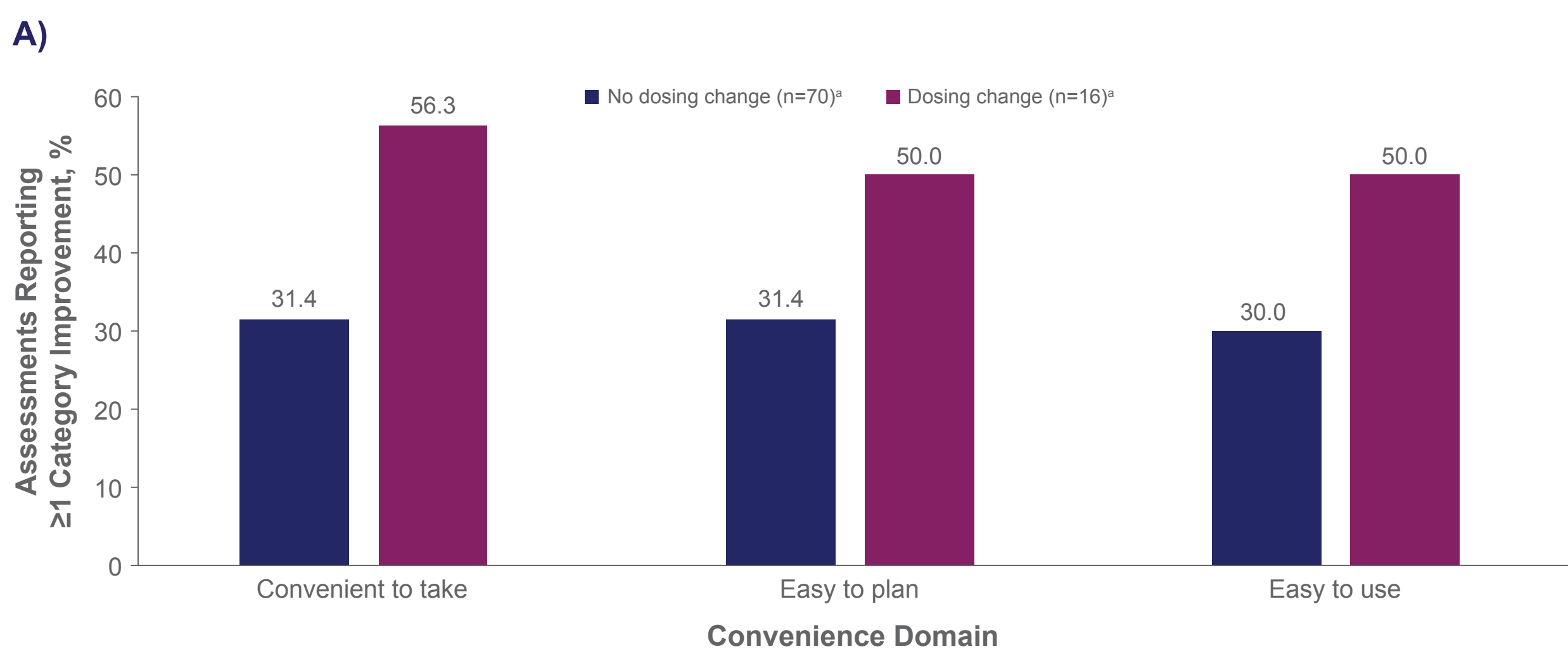
Figure 4. Most Participants Did Not Have an LXB Dosing Change Since Enrollment



*Percentages may not sum to 100% because participants could select multiple response options. ^aA change in dosing time may include changes to the timing of first and/or second nightly doses. ^bA change in dosing amount may include changes to individual dose amounts and/or a change in total nightly dosage. LXB, low-sodium oxybate.

- Of the 51 participants with dosing change data, 12 (23.5%) reported a change to their LXB dosing regimen, in consultation with their healthcare provider, at weeks 12 or 24
- Among the 12 participants who reported LXB dosing changes during the study, the most common adjustment was a change in their dosing amount

Figure 5. Improvement in TSQM-9 Response Categories From Enrollment to Weeks 12 or 24, Among Those With and Without an LXB Dosing Change^{a,b}



^aThe 12 participants who had LXB dosing regimen adjustments at weeks 12 or 24 contributed 16 follow-up assessments; 70 follow-up assessments were contributed by 45 participants who did not have a dosing change. As there were 2 follow-up timepoints, a participant could report no dosing change at week 12 and still confirm a dosing change at week 24. Percentages reflect the proportion of assessments at weeks 12 and 24, as opposed to the proportion of participants. ^bResults indicate improvement of at least one response category (eg, from “satisfied” to “very satisfied”).

LXB, low-sodium oxybate; TSQM-9, 9-Item Treatment Satisfaction Questionnaire for Medication.

- Overall, improvements in treatment satisfaction were reported over time among participants
- Participants who adjusted their LXB dosing regimens more frequently reported improvements in treatment convenience and effectiveness than those without dosing changes

Figure 6. Interview Participants Described Their Experience With LXB Titration and Individualized Dosing



LXB, low-sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2.

- At enrollment, all 15 interview participants reported shared decision-making with their healthcare providers
 - The most common consideration for dose adjustment during titration was sleep quality (46.7%), followed by slower titration (26.7%) and side effect management (26.7%)
- At enrollment, 10 of 12 (83.3%) interview participants reported that individualized dosing was beneficial for their lifestyle, offering greater control and freedom

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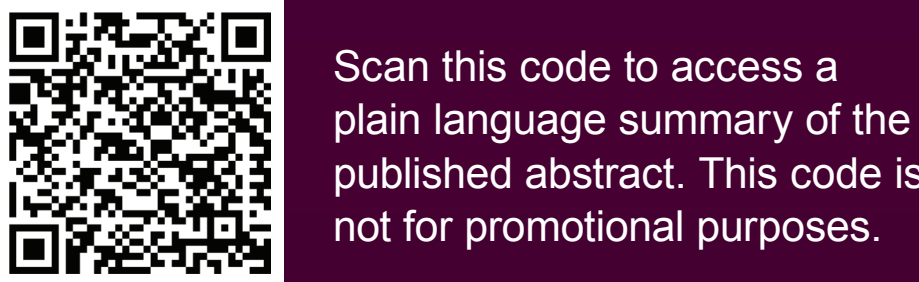
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Supplemental Results

Supplemental Table 1. Additional Participant Characteristics

Characteristic	Participants With Narcolepsy (N=59)
Age (years)	
Mean (SD)	34.7 (8.9)
Median (range)	34.0 (21.0–55.0)
Narcolepsy subtype, n (%)	
NT1	30 (50.8)
NT2	29 (49.2)
Gender, n (%)	
Female	54 (91.5)
Male	5 (8.5)
Race, n (%)	
White	54 (91.5)
Multiracial	2 (3.4)
Other	2 (3.4)
Prefer not to answer	1 (1.7)
Employment, n (%) ^a	
Working full-time	43 (72.9)
Student	7 (11.9)
Seeking work opportunities	5 (8.5)
Working part-time	6 (10.2)
Other	6 (10.2)
Homemaker	3 (5.1)
Retired	1 (1.7)
Unable to work	1 (1.7)
Number of LXB doses per night, n (%)	
1	1 (1.7)
2	57 (96.6)
3	1 (1.7)
Number of weeks taking LXB	
Mean (SD)	99.0 (73.4)
ESS score	
Mean (SD)	10.5 (4.3)
Other current comorbid diagnoses, n (%) ^a	
Attention deficit disorder/attention deficit hyperactivity disorder	9 (15.3)
Anxiety	21 (35.6)
Depression	13 (22.0)
Hyperlipidemia/high cholesterol	2 (3.4)
Hypertension	5 (8.5)
Obesity	7 (11.9)
Obstructive sleep apnea	10 (16.9)
Periodic limb movement disorder	1 (1.7)
Restless leg syndrome	3 (5.1)
Current concomitant treatments, n (%) ^a	
Amphetamine	19 (32.2)
Armodafinil	4 (6.8)
Fluoxetine	6 (10.2)
Methylphenidate	3 (5.1)
Modafinil	6 (10.2)
Pitolisant	6 (10.2)
Sertraline	7 (11.9)
Solriamfetol	8 (13.6)
Venlafaxine	5 (8.5)
Other current treatment	5 (8.5)
None of the above ^b	14 (23.7)

^aResponse options are not mutually exclusive. ^b“None of the above” indicates that participants were not taking any of the medications listed in this table; however, they may have been taking other concomitant medications.
ESS, Epworth Sleepiness Scale; LXB, low-sodium oxybate; NT1, narcolepsy type 1; NT2, narcolepsy type 2; SD, standard deviation.



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